



Atty. Dkt. No. 029318-0976

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ray W. WOOD et al.

Title: NANOPARTICULATE BECLOMETHASONE
COMPOSITIONS (AS AMENDED)

Appl. No.: 10/667,472

Filing Date: 09/23/2003

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop PATENT APPLICATION
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56 or cited by or submitted to the U.S. PTO in parent application Serial No. 09/577,489, filed 05/25/2000. As provided in 37 CFR §1.98(d), copies of the Documents A1 – A24 and A26 – A58 are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application. A copy of Document A25 is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

The listed documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Dec 11, 2003

By Michele M. Simkin

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Registration No. 34,717

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: December 11, 2003

(use as many sheets as necessary)

Complete if Known

Application Number	10/667,472
Filing Date	09/23/2003
First Named Inventor	Ray W. Wood
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	029318-0976

 Sheet **P E** 1 of 3
U.S. PATENT DOCUMENTS

Examiner Initials* TRADEMARK OFFICE	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	5,145,684		LIVERSIDGE ET AL.	09/1992	
	A2	5,091,187		HAYNES	02/1992	
	A3	5,091,188		HAYNES	02/1992	
	A4	4,807,814		Douche <i>et al.</i>	02/28/1989	
	A5	4,826,821		Clements	05/02/1989	
	A6	5,118,528		Fessi <i>et al.</i>	06/02/1992	
	A7	5,202,110		Dalby <i>et al.</i>	04/13/1993	
	A8	5,225,183		Purewal <i>et al.</i>	07/06/1993	
	A9	5,260,478		Bacon <i>et al.</i>	11/09/1993	
	A10	5,264,610		Bacon	11/23/1993	
	A11	5,300,739		Bittar	04/05/1994	
	A12	5,322,679		Bacon <i>et al.</i>	06/21/1994	
	A13	5,518,738		Eickhoff <i>et al.</i>	05/21/1996	
	A14	5,747,001		Wiedmann <i>et al.</i>	05/05/1998	
	A15	5,785,049		Smith <i>et al.</i>	07/28/1998	
	A16	5,985,309		Edwards <i>et al.</i>	11/16/1999	
	A17	5,264,213		Shibahara <i>et al.</i>	11/23/1993	
	A18	5,098,907		Kondo <i>et al.</i>	03/24/1992	
	A19	5,002,952		Kondo <i>et al.</i>	03/26/1991	
	A20	4,983,605		Kondo <i>et al.</i>	01/08/1991	
	A21	4,904,668		Kondo <i>et al.</i>	02/27/1990	
	A22	4,851,421		Iwasaki <i>et al.</i>	07/25/1989	
	A23	4,727,077		Haga <i>et al.</i>	02/23/1988	
	A24	4,540,602		Motoyama <i>et al.</i>	09/10/1985	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A25	WO	02/098565	A1	ELAN PHRMA INTERNATIONAL LIMITED	12/12/2002		
	A26	WO	92/08446	A1	GLAXO GROUP LIMITED	05/29/1992		
	A27	EP	0 602 702	A1		12/1993		
	A28	GB	2 237 510	A		05/1991		

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: December 11, 2003 <i>(use as many sheets as necessary)</i>	Complete if Known												
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td>10/667,472</td> </tr> <tr> <td>Filing Date</td> <td>09/23/2003</td> </tr> <tr> <td>First Name of Inventor</td> <td>Ray W. Wood</td> </tr> <tr> <td>Group Art Unit</td> <td>Unassigned</td> </tr> <tr> <td>Examiner Name</td> <td>Unassigned</td> </tr> <tr> <td>Attorney Docket Number</td> <td>029318-0976</td> </tr> </table>	Application Number	10/667,472	Filing Date	09/23/2003	First Name of Inventor	Ray W. Wood	Group Art Unit	Unassigned	Examiner Name	Unassigned	Attorney Docket Number	029318-0976
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		Number ⁴	Kind Code ⁵ (if known)				
	A29	WO	91/16038		10/1991		
	A30	DE	43 27 063	A1	02/1995		
	A31	WO	94/20072		09/1994		
	A32	WO	95/27475		10/19/1995		
	A33	WO	96/25918		08/29/1996		
	A34	WO	98/35666		08/20/1998		
	A35	WO	99/30687		06/24/1999		
	A36	WO	99/38493		08/05/1999		
	A37	WO	99/45779		09/16/1999		
	A38	EP	0 275 796		07/27/1998		
	A39	EP	0 347 779		12/27/1989		
	A40	EP	0 499 299	A2	08/19/1992		
	A41	EP	0 262 560		04/06/1998		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A42	Stephen P. Newman, Chapter 9, "Therapeutic Aerosols," in Aerosols and the Lung, Clarke et al., eds., pp. 197-224 (Butterworths, London, England, 1984)	
	A43	Prodi et al., "Airborne Particles And Their Intrapulmonary Deposition", in Scientific Foundations Of Respiratory Medicine, J. G. Scadding ed., pp. 545-558 (W.B. Saunders Co., Philadelphia, PA 1981)	
	A44	J. Heyder, "Mechanisms Of Aerosol Particle Deposition", Lung Mucociliary Clearance, 80(6):820-823 (1981)	
	A45	Fox et al., "Performance Of A Venturi Eductor As A Feeder In A Pneumatic Conveying System," Powder And Bulk Engineering, pp. 33-36 (1988)	
	A46	Tiano, "Functionality Testing Used To Rationally Assess Performance Of A Model Respiratory Solution Or Suspension In A Nebulizer (Performance Assessment)," Vol. 56/12-B of Dissertation Abstracts International (1995)	
	A47	Waldrep et al., "Operating Characteristics of 18 Different Continuous-Flow Jet Nebulizer With Beclomethasone Dipropionate Liposome Aerosol," Chest, 105(6):106 (1994)	
	A48	P. Byron, "Aerosol Formulation, Generation, And Delivery Using Nonmetered Systems," Respiratory Drug Delivery, 144-151 (CRC Press, 1989)	

Examiner
Signature

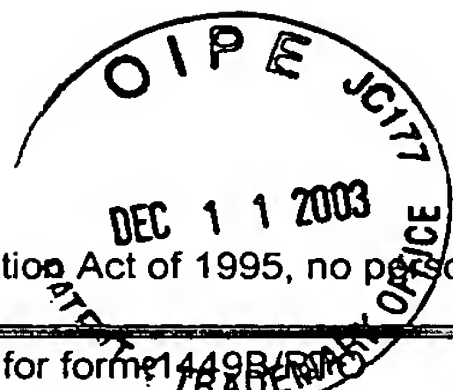
Date
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A49	Soviet Union Patent No. 628930, for "Bulb-Actuated Ejector For Powdered Medicinal Substance" (1978)	
	A50	F. Moren, Chapter 13, "Aerosol Dosage Forms and Formulations," Aerosols in Medicine. Principles, Diagnosis and Therapy, 2nd Edition, F. Moren et al. eds. (Elsevier Science Publishers 1993)	
	A51	Remington's Pharmaceutical Sciences, pp. 1565-1567 (Mack Publishing Company 1990)	
	A52	Edwards et al., "Large Porous Particles for Pulmonary Drug Delivery," Science, 276:1868-1871 (June 20, 1997)	
	A53	"Test Method B527-93(2000)e1 Standard Test Method for Determination of Tap Density of Metallic Powders and Compounds," http://www.astm.org/DATABASE.CART/PAGES/B527.htm	
	A54	"Autotap and Dual Autotap," http://www.quantachrome.com/Density/Autotap.htm	
	A55	"Optimal Tapped Density Tester," http://optimalcontrol.com/tapped.html	
	A56	N. Kondo et al, "Improved Oral Absorption of a Poorly Water-Soluble Drug, HO-221, by Wet-Bead Milling Producing Particles in Submicron Region," <u>Chem. Pharm. Bull.</u> , 41(4), pgs. 737-740, 1993.	
	A57	N. Kondo et al, "Pharmacokinetics of a Micronized, Poorly Water-Soluble Drug, HO-221, in Experimental Animals," <u>Chem. Pharm. Bull.</u> , 16(8), pgs. 796-800, 1993.	
	A58	N. Kondo et al, "Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug," <u>Journal of Pharmaceutical Sciences</u> , 83(4), pgs. 566-570, © American Chemical Society and American Pharmaceutical Association, 1993.	

Examiner Signature		Date Considered	
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